

COVID-19 Vaccine Information Brief

August 10, 2023

IMPORTANT/NEW COVID-19 Vaccine Information

- Moderna Bivalent Vaccine for Under 6 Years of Age - Shelf-Life Extensions
- No August COVID-19 Vaccine Allocation
- Reminders Regarding Current COVID-19 Vaccine Program Provider Agreement
- COVID-19 Vaccine Inventory and Disposal
- Pfizer Expiration Date Extension
- Action Steps for Iowa COVID-19 Providers

Moderna Bivalent Vaccine for Under 6 Years of Age - Shelf-Life Extensions

The FDA has approved Moderna's request for a 3-month shelf-life extension for all Moderna under 6 years of age COVID-19 vaccines in the lots identified in the table below. Moderna has updated the [Vial Expiration Checker](#) tool to reflect the extension for the four lots listed below. Only the lot numbers below are included in this shelf-life extension approval.

Lot Number	Expiry Date Prior to Extension	Extended Expiration Date
201L22A	September 6, 2023	December 6, 2023
214K22A	August 29, 2023	November 29, 2023
215K22A	August 19, 2023	November 19, 2023
216K22A	August 22, 2023	November 22, 2023

- [Moderna Vial Expiration Checker](#)
- [Pfizer-BioNTech COVID-19 Vaccine Expiry Checker](#)
- [Novavax Expiry Date Checker](#)

No August COVID-19 Vaccine Allocation

In preparation for the [commercialization of COVID-19 vaccines](#) in mid to late September 2023, **there will be no August COVID-19 Vaccine Allocation**. It is anticipated overall demand for the current COVID-19 vaccine will significantly decrease for the general population in late summer. LPHAs should work with providers in their county to:

- **Plan to use existing inventory as much as possible.**
 - The Iowa Immunization Program encourages providers to not miss any opportunities to vaccinate every eligible person who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.
 - **Collaborate to redistribute COVID-19 vaccine inventory to prevent vaccine wastage.**
 - Instructions for LPHAs to view provider IRIS inventory, along with COVID-19 Vaccine inventory maps, are posted to the HAN *3 COVID-19 Vaccine folder under the *I Vaccine Inventory Maps.
 - **Continue to monitor inventory.** Vials of vaccine that exceed the shelf-life indicated by the manufacturer should be disposed of as regulated medical waste in consultation with the manufacturer.
 - Report all disposed inventory as “Open vial but all doses not administered”. Healthcare providers can use the IRIS [Adjusting COVID-19 Vaccine Inventory for Wastage](#) instructions to account for these doses. IRIS staff are available to help manage IRIS inventory by calling 800-374-3958.
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Reminders Regarding COVID-19 Vaccine Program Provider Agreement

Over the last two years, healthcare partners have effectively implemented the largest adult vaccination program in U.S. history, with over 270 million people receiving at least one shot of a COVID-19 vaccine. Since January 2021, COVID-19 deaths have declined by 95% and hospitalizations are down nearly 91%. While it is anticipated commercialization will occur in the fall, **at this time the CDC COVID-19 Vaccine Program remains unchanged.**

While many individuals may wait to receive a COVID-19 vaccine until the updated version is released, as it is expected to provide more robust protection against currently circulating variants, certain individuals may need or desire a COVID-19 vaccine prior to the anticipated release of the updated vaccine in the fall. CDC wants to ensure that providers in the

COVID-19 Vaccination Program are not denying requests or turning away patients from obtaining COVID vaccine under this federal program. The CDC COVID-19 Vaccination Program Provider Agreement requires that healthcare providers abide by the terms of the agreement, which states that COVID-19 vaccines are provided at 100% no cost to the vaccine recipient.

COVID-19 vaccination providers cannot charge vaccine recipients for the vaccine for any administration fees, copays, or coinsurance. COVID-19 vaccination providers cannot deny vaccination to anyone who does not have health coverage, is underinsured, or is out of network. The federal PHE for COVID-19 expired on May 11, 2023; however, [CDC's COVID-19 Vaccination Program Provider Agreement](#) requires that all organizations and providers participating in the CDC COVID-19 Vaccination Program:

- **must** administer COVID-19 Vaccine at no out-of-pocket cost to the recipient
- **may not deny** anyone vaccination based on the vaccine recipient's coverage status or network status
- **may not charge** an office visit or other fee if COVID-19 vaccination is the sole medical service provided
- may **not** require additional medical services to receive COVID-19 vaccination
- **may** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
 - vaccine recipient's private insurance company
 - Medicare or Medicaid reimbursement
- may **not** seek any reimbursement, including through balance billing, from the vaccine recipient

COVID-19 Vaccine Inventory and Disposal

Healthcare providers should maintain current inventories of EUA and/or BLA vaccines until the vaccine exceeds its shelf life, or the FDA announces a change to EUAs and/or BLAs, whichever occurs first. Any vial of vaccine that exceeds the shelf-life indicated by the manufacturer should be disposed of as regulated medical waste. The COVID-19 Vaccination Provider Agreement states that providers should dispose of COVID-19 vaccine waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste. This agreement requires providers to report wastage, including doses disposed of due to expiration.

The federal government does not have a method to return wasted or expired COVID-19 vaccines. To minimize the risk of administration error, providers should:

- Dispose of all expired COVID-19 vaccine vials in accordance with local, state, and federal regulations.
- Report all disposed inventory as “Open vial but all doses not administered”. Healthcare providers can use the IRIS [Adjusting COVID-19 Vaccine Inventory for Wastage](#) instructions to account for these doses. IRIS staff are available to help manage IRIS inventory by calling 800-374-3958.

Resources

[Moderna Vial Expiration Checker](#)

[Novavax Expiry Date Checker](#)

Action Steps for Iowa COVID-19 Providers

The Iowa Immunization Program acknowledges many details regarding the commercialization of COVID-19 vaccines have not been released from the USG. The Program encourages COVID-19 providers to take the following action steps to prepare for the commercialization of COVID-19 vaccines. The Program remains committed to providing updates as information becomes available.

- **Plan to use existing inventory as much as possible as there will be NO COVID-19 Vaccine Allocation in August.**
 - **Many individuals will wait to receive a COVID-19 vaccine until the updated version is released, as it is expected to provide more robust protection against currently circulating variants.** The Iowa Immunization Program encourages providers to continue efforts to minimize unnecessary wastage; however, do not miss any opportunities to vaccinate every eligible person who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.
- **Collaborate to redistribute COVID-19 vaccine inventory to prevent vaccine wastage.**
 - Instructions for LPHAs to view provider IRIS inventory, along with COVID-19 Vaccine inventory maps, are posted to the HAN *3 COVID-19 Vaccine folder under the *I Vaccine Inventory Maps.
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instructions to account for these doses. IRIS staff are available to help manage IRIS inventory by calling 800-374-3958.

- **Share ancillary kits or items contained within, with other immunization programs within the practice, clinics and other sites offering healthcare services, or veterinary clinics.** Ancillary kits cannot be donated outside of the U.S. or to organizations that will use the supplies outside the U.S. The Iowa Immunization Program has no means to collect or dispose of ancillary supplies.